

5 14 3 100 7.7 29 20 25

July 14, 2003

RECEIVED
AUG 0 7 2003
BY:

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

Pharmavite Reference: 14160 L40 AA

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:

  Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- Text of the statement(s):

  The German Commission E has approved Asian ginseng and its preparations as a tonic for invigoration and fortification in times of fatigue and debility, for declining capacity for work and concentration, and also for use during convalescence. The World health Organization (WHO) has determined that the following issues of Asian ginseng are supported by clinical data: prophylactic and restorative agent for enhancement of mental and physical capacities, in cases of weakness, exhaustion, tiredness, and loss of concentration, and during convalescence.
- (3) Name of the dietary ingredient(s):
  Asian (Korean White) ginseng root extract (Panax ginseng)
- (4) Name of the dietary supplement(s):
  Products containing Asian (Korean White) Ginseng as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, Target, TruNature, Walgreens.

85614



Re: 14160 L40 AA July 14, 2003

Page 2

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

David Kropp

Director, Regulatory and Consumer Affairs

cc. P. Bolar